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FDA stalls over-the-counter distribution of "morning-after" pills

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By The Leader-Chicago Bureau (admin@illinoisleader.com)

WASHINGTON -- While conservatives' first reaction to the **Federal Drug Administration's** refusal to allow the "morning-after" contraceptive pill to be sold over the counter was relief, the FDA's announced position may not be final.

The FDA reports last week's decision to continue the current restriction on over-the-counter "Plan B" contraceptive distribution was based on insufficient data provided in Barr Lab's application.

"Although we did not have sufficient data to approve this application now, I will be working toward the expeditious evaluation of Barr's response to the Not Approvable letter," **Dr. Steven Galson**, Acting Director of FDA's Center for Drug Evaluation and Research (CDER), said.

Galson said that if Plan B is approved for nonprescription use, it would dramatically increase access to this product and will represent an important incremental step forward in contraceptive availability in the United States.

"Wide availability of safe and effective contraceptives is important to public health. I look forward to supporting CDER's important continued role in ensuring improved availability of these products," Galson said.

But today, **Congressman Don Manzullo (R-IL)** congratulated the **U.S. Food and Drug Administration** for denying Barr Lab's request to make the morning-after pill available without prescription.

The FDA cited a lack of data on the drug's use among girls under 16 years old who could purchase the morning-after pill over the counter. Currently, the morning-after pill is distributed in the United States through prescription. A minor seeking the drug today has to first visit a doctor.

"Birth control pills are sold through prescription and require doctor visits because of their potential health risks, including blood clots, stroke and heart attacks," Manzullo said. "The morning-after pill is more powerful than prescription birth control pills with even greater health risks. I applaud the FDA for recognizing the dangers this drug could pose without doctor supervision, especially to young girls."

Manzullo became embroiled in the controversy concerning the distribution of contraceptives to minors six years ago when authorities discovered that a 37-year-old high school teacher in his home district's town of **Crystal Lake** was taking a 14 year old girl to a **Planned Parenthood** clinic repeatedly for birth control injections. The teacher and the minor student were involved in a sexual relationship.

As a result of Manzullo's efforts, in 1998 Congress passed a law requiring federally funded clinics to follow state requirements for reporting cases of sexual abuse.

While several women's groups encouraged the FDA to allow easier access to the morning-after pill, **Concerned Women for America (CWA)** testified against widespread distribution of the drug.

"The FDA is right to be cautious about making a potent drug that can harm women available next to candy bars and toothpaste," said **Wendy Wright**, CWA's Senior Policy Director. "We are very grateful that the FDA put concern for women's health over political pressure.

"We have exposed numerous medical and public health problems with the morning-after pill. Having the morning-after pill easily available would make guinea pigs of unsuspecting women," Wright said.

The FDA recognized the health risk to teen girls, but should also consider the risk of sexual abuse in any further petition by the makers of Plan B.

"The possibility of sexual abuse should be considered routinely in every adolescent female patient who has initiated sexual activity," stated **Dr. Joycelyn Elders** in the ***Journal of the American Medical Association***.

Surveys indicate, CWA said, men are the most frequent buyers of the morning-after pill in countries which allow its over-the-counter sale.

Although U.S. law prohibits FDA from discussing pending applications because they contain commercial confidential information, in this instance the sponsor of Plan B, Barr Research, allowed the FDA to comment in general terms on the status of Barr's application to make Plan B available as an OTC product and on the agency's action.